Observational Study

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Efficacy of modified pressure cuff for thrombolytic treatment on lower extremity deep venous thrombosis

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Abstract

To compare the effectiveness and patient comfort between two methods that block superficial venous blood flow during the thrombolytic treatment of lower extremity deep venous thrombosis (DVT) to provide evidence that informs clinical choice.

One hundred twenty patients with lower extremity DVT were randomly divided into sphygmomanometer (group A, n=40), tourniquet (group B, n=40), and control group (no blocking, n=40). All the patients were treated with a daily dosage of urokinase using a dial sphygmomanometer cuff and tourniquet to block lower extremity superficial vein blood flow. The pressure of the dial sphygmomanometer blocking lower extremity superficial vein blood flow was measured during lower extremity venography. Leg swelling reduction rate, venous patency, thrombus removal rate, and average comfort index were observed during the blocking process.

The average pressure value for group A was 70 ±10 mm Hg. The differences in the swelling reduction rate and venous patency were significant between the groups. Comparing the two groups at different time points, the average thrombus clearance rate of group A was higher than that of group B and control group. The leg pain scores of group A were lower than those of group B and control group. The postoperative comfort ratio of group A was higher than that of group B, and the proportion of severe discomfort in group A was lower than that in group B.

Compared with the tourniquet, using a dial sphygmomanometer cuff to block lower extremity superficial vein blood flow achieved a better thrombolytic effect on DVT and provided higher patient comfort during treatment.

Abbreviations: CDT = catheter-directed thrombolysis, DVT = deep venous thrombosis, MAT = manual aspiration thrombectomy, PE = pulmonary embolism, PTS = post-thrombotic syndrome, VAS = visual analog scale.

Keywords: dial sphygmomanometer, lower extremity DVT, superficial vein blood flow blocking, thrombolytic therapy, tourniquet

1. Introduction

Lower extremity deep venous thrombosis (DVT) treatment is used to reduce the swelling and pain of the affected limb, in order to prevent the occurrence of pulmonary embolism (PE), post-thrombotic syndrome (PTS), and recurrent venous thrombosis.[1–7] Previous studies have confirmed that anticoagulation and thrombolytic therapy is the most common method for the treatment of DVT.[8–12] Anticoagulant therapy, aiming to reduce the recurrence of PE and DVT, is the standard treatment of DVT. But it often leaves the PTS sequel, including different levels of pain, swelling, pigmentation, and ulceration. Moreover, thrombolysis therapy, opening block vessels fully or partially, can alleviate limb symptoms as soon as possible and protect the function of venous valves and reduce the incidence of PTS.[2,13–18] Furthermore, the standard clinical guideline utilizes the low dose urokinase (500,000 U/day) and extended period (4–10 days) of continuous thrombolytic therapy by using intravenous infusion pump in the dorsal foot superficial vein of the affected limb.[8,19,20] During the process of thrombolysis therapy, blocking the superficial vein blood flow above the ankle joint of the affected limb can make the thrombolytic agent act more efficaciously on the local thrombus in deep vein.[4,8,10,19]

Prior researches have demonstrated that the assistance of tourniquet with urokinase thrombolysis has become a prevailing technique for thrombolytic therapy on DVT.[21–25] However, the efficiency of thrombolytic therapy and the patient comfort is still lack of consensus. In recent years, an agreement on the guideline for the interventional treatment of DVT has been carried out by Chinese Medical Association Chinese Society of Radiology Interventional Group, which does not recommend the optimal nursing tool for thrombolytic therapy.[8,19] Therefore, there still remains much controversy about the thrombolytic nursing tool on DVT treatment for clinical use.

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Therefore, in the present study, we aimed to explore a novel nursing method for blocking superficial venous blood flow during the thrombolytic treatment of lower extremity DVT patients and to compare this method with the commonly used tourniquet tool to obtain a better thrombolytic effect and to raise patients' comfort levels during treatment. The hypothesis of the study is that using the dial sphygmomanometer cuff to block the superficial vein of the lower extremity blood flow will provide a better thrombolytic effect for patients after DVT treatment.

2. Materials and methods

2.1. Patients

Eighty patients diagnosed with DVT for the first time between January 2018 and December 2019 at the Department of Vascular and Interventional Radiology, Nanjing First Hospital, were consecutively selected. All the patients were treated with low-dose urokinase thrombolysis and had a follow-up clinical data for at least 12 months. The selection criteria included:

1. patients were less than 75 years of age;
2. unilateral and pronounced limb swelling;
3. disease duration within 28 days;
4. confirmed by invasive venography for DVT that the thrombus was located in common iliac, external iliac, femoral veins, and popliteal vein.

The exclusion criteria included:

1. a history of cerebral hemorrhage and/or surgery within 3 months;
2. a history of digestive tract and other internal bleeding and/or surgery within 1 months;
3. serious infection, local skin damage, and acute inflammation reaction of the affected limb;
4. refractory hypertension (blood pressure > 180/110 mm Hg).

Approval for the study was obtained by the Ethics Committee of the Nanjing Medical University (NO. QX20120928–07). Written informed consent from patients or their families was obtained.

The locoregional pharmological thrombolysis was applied in this study. The urokinase was administered directly into the dorsalis pedis vein in the foot of the affected limb in order to minimize the rate of side effects due to the drug. Normal saline 500 mL plus urokinase 500,000 U/day (250,000 U/vial, China Livzon Pharmaceutical Group, Inc) was administrated using intravenous infusion pump (ZNB-XD, Beijing KellyMed Co, Ltd) through continuous infusion into the dorsal foot superficial vein of the affected limb via indwelling needle with a flow rate of 20 mL/h. In addition to thrombolytic therapy, all patients received subcutaneous injection of low molecular heparin calcium (Hebei Changshan Biochemical Pharmaceutical Co, Ltd) with a dose of 4100 U/12 h of anticoagulation therapy. The blood coagulation function was monitored daily during thrombolytic therapy.[26,27]

Thrombolytic therapy was terminated if we met the following criteria:

1. the swelling and pain of the affected limb disappeared and intravenous angiography showed complete removal of venous thrombus, blood flow restoration, and lumen patency;
2. venous inflammation, bleeding, and other complications during thrombolytic treatment;
3. After continuous treatment for 5 days, swelling of the affected limb had no obvious improvement and the angiography showed no changes of venous thrombosis;
4. fibrinogen coagulation function <1.0 g/L.

2.2. Research methods

The patients were divided into a sphygmomanometer group (group A) with 40 cases and a tourniquet group (group B) with 40 cases, according to the different therapeutic methods. 40 patients who have no blood flow blocking during the thrombolytic treatment were regarded as controls. The baseline parameters of the patients from the two groups were comparable.

Group A mode: A dial sphygmomanometer (XJ-B Jiangsu Yuanyan Medical Equipment Co, Ltd) was used to block the superficial venous blood flow during the thrombolysis treatment of the dorsal foot superficial vein. The length of the sphygmomanometer cuff was 65 cm, the length of the airbag was 35 cm, and the width of the cuff and airbag was 7 cm. To control the tightness for different procedures, we maintained the pressure within one range. The range of the pressure was 65 to 75 mm Hg (70 ± 5 mm Hg). The sphygmomanometer cuff was bound on the affected limb 15 cm above the ankle joint, with 15 min spent inflating and 15 min spent deflating by turns. The pressure of the sphygmomanometer was measured during the lower limb venography, namely, the air sac pressure while the lower extremity deep veins showed. The pressure value was taken at 10 times the integral for clinical convenience.

Group B mode: A silicon strap was used to block the superficial venous blood during the thrombolysis treatment of the dorsal foot superficial vein. The silicon strap was ligated on the affected limb 15 cm above the ankle joint, with 15 min of ligation and 15 min of loosening by turns.

Control group: For the patients with severe swelling and pain, local skin ulceration and other factors who cannot tolerate the blocking method, only 500 mL of normal saline + urokinase 250,000 U/D was used for infusion through the patient's leg superficial vein indwelling needle infusion pump, with a flow rate of 20 mL/h and 24 h of continuous use.

To ensure the standardization and unification of the technical operation, three nurses in the study received standard training for selecting and assessing the ligation site and for learning the procedures for the sphygmomanometer and the tourniquet methods.

2.3. Clinical evaluation

1. Limb swelling rate: we measured the circumference of the affected and the healthy limbs 15 cm above and 10 cm below the edge of the patella and calculated the circumference differences between limbs before and at the end of the treatment. Limb swelling rate = (circumference difference before thrombolysis − circumference difference after thrombolysis) / circumference difference before thrombolysis × 100%.
2. Venous patency: it was evaluated using the criteria proposed by Porter and Moneta.[28] The method is as follows: venography evaluation shows complete patency: 0 point; partial patency: 1 point; no patency: 2 points. Venous patency = (venous patency score before thrombolysis − venous

patency score after thrombolysis) / venous patency score before thrombolysis × 100%.

3. Thrombus clearance rate: the thrombus clearance rate was evaluated by senior interventional physicians according to the preoperative and postoperative angiographic imaging. Thrombolysis classification: grade III: thrombus clearance rate > 95%; grade II: most of the thrombus dissolving, thrombus clearance rate 50% to 95%; grade I: part of thrombus dissolving, thrombus clearance rate <50%.
4. Patient comfort scores: the patient comfort was scored from the two groups across the thrombolytic treatment, according to patients' subjective perception of the pain degree at the puncture point, capillary hemorrhage, sphygmomanometer cuff or tourniquet ligation discomfort, and patients' body tolerance degree. Scoring rules: no obvious discomfort: 0 point; mild discomfort: 1 to 3 points; moderate discomfort: 4 to 6 points; severe discomfort: 7 to 9 points; insufferable: 10 points.
5. Visual analog scale (VAS): the degree of the leg was assessed using VAS method. Scoring rules: no pain: 0 point; mild pain: ≤4 points; moderate pain: 5 to 6 points; severe pain: ≥7 points; sharp pain: 10 points.

2.4. Statistical analyses

In order to check the normality of demographic data distribution, the Kolmogorov–Smirnov test was performed. One-way analysis of variance (ANOVA) and the chi-squared (χ^2) test was used to investigate the differences among three groups. Post hoc analysis was performed within any two groups. The continuous variables which were not normally distributed were analyzed by Kruskal–Wallis test among groups. The SPSS software (version 20.0; SPSS, Chicago, IL) was used for statistical analyses, $P<.05$ was considered statistically significant.

3. Results

The demographics of the patients were shown in Table 1. There were no significant differences in gender, age, body mass indexes (BMI), side of DVT, and type of thrombosis among group A, group B, and control group (all $P>.05$).

To ensure that all groups of patients had a similar severity of DVT, pre-lysis lower extremity venography was performed in three groups to measure the thrombus scores. There were no significant differences in thrombus scores in the common and external iliac veins, common femoral veins, proximal and distal superficial femoral veins, and popliteal veins or in the total scores among the three groups (all $P>.05$). The lower extremity venography of group A showed that the lower extremity deep veins appeared when the pressure value of the sphygmomanometer ranged from 60 to 80 mm Hg (Fig. 1).

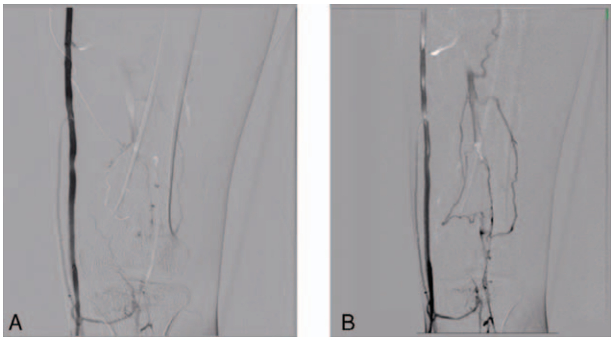

Figure 1. The lower extremity deep veins of group A appeared when the pressure value of dial sphygmomanometer ranged from 60 mm Hg (A) to 80 mm Hg (B).

In the comparisons of limb swelling rate and venous patency before and after the thrombolytic treatment, we observed significant differences among the three groups in both limb swelling rate ($P=.025$) and venous patency ($P=.010$) (Table 2). After post hoc analysis, significant differences were observed between two groups (all $P<.05$).

After comparing the average thrombus clearance rates at different time points after the thrombolytic therapy using the same urokinase dose, there were significant differences among the three groups (all $P<.05$) (Table 3). After post hoc analysis, significant differences were observed between two groups in any single day (all $P<.05$).

Furthermore, in the comparison of the postoperative comfort degree of patients' calves among the three groups, we found that the comfort ratio of group A was significantly higher than that of group B, while the proportion of severe discomfort of group A was significantly lower than that of group B (all $P<.05$) (Table 4).

In the comparison of the postoperative VAS scores between the two groups, postoperative calf pain scores at different time points in group A were significantly lower than those in group B (all $P<.05$) (Table 5).

4. Discussion

The present study explored a novel and feasible blocking method in clinical for superficial venous blood flow during thrombolytic

Table 1

The demographics of the patients.

Parameters	Group A (n=40)	Group B (n=40)	Controls (n=40)	P
Male/female	22/18	23/17	22/18	.997*
Age (mean ± SD)	58.52 ± 4.74	59.13 ± 5.61	56.81 ± 4.78	.130†
BMI (mean ± SD)	23.77 ± 3.41	24.14 ± 5.14	23.37 ± 4.54	.685†
Side of DVT (left/right)	28/12	29/11	28/12	.961*
Type of thrombosis, n (%)				
Peripheral	21 (52.5)	20 (50.0)	22 (55.0)	.905*
Central	11 (27.5)	10 (25.0)	11 (27.5)	.958*
Mixed	7 (17.5)	8 (20.0)	6 (15.0)	.841*

* Indicates data obtained with Chi-square test.
† Indicates data obtained with analysis of variance.

Table 2

Comparison of limb circumference difference, swelling rate and venous patency before and after thrombolytic treatment of the three groups.

Group	Number of cases	Limb swelling condition				Venous patency		
		Preoperative circumference difference (cm)	Postoperative circumference difference (cm) Mean	Range	Swelling rate (%)	Preoperative score (score)	Postoperative score (score)	Patency rate (%)
Controls	40	6.11±1.69	1.4	0–6.75	58.30±11.25	1.75±0.43	0.93±0.52	58.75±33.33
Group A	40	5.95±3.61	1.4	0–6.84	86.12±20.46	1.73±0.45	0.28±0.45	86.25±20.61
Group B	40	5.87±3.09	1.5	0–6.71	71.21±21.10	1.65±0.44	0.43±0.47	75.72±20.71
P value					0.025*			0.010*

Data are expressed as mean±SD.
* $P<.05$.

Table 3

Comparison of average thrombus clearance rate before and after thrombolytic therapy of the three groups.

Group	Number of cases	Urokinase dosage (U/d)	Average of thrombus clearance rate (%) 2d	4d	6d	8d	10d	*P*
Controls	40	500,000	23.38±6.93	42.8±8.28	66.63±6.93	79.50±4.72	83.38±3.77	<.001*
Group A	40	500,000	32.63±13.73	57.38±17.30	78.19±13.26	90.58±10.42	95.00±13.26	
Group B	40	500,000	27.50±11.98	49.38±15.41	72.00±12.86	82.27±17.34	86.00±14.08	

Data are expressed as mean±SD.
* $P<.001$.

Table 4

Comparison of postoperative comfort of patients' calf in the three groups.

Group	Number of cases	No discomfort	Mild discomfort	Moderate discomfort	Severe discomfort
Controls	40	40 (100)	0	0	0
Group A	40	10 (25)	25 (62.5)	5 (12.5)	0
Group B	40	0	15 (37.5)	20 (50.0)	5 (12.5)
P					<.001*

Data are expressed as n (%).
* $P<.001$.

treatment on lower extremity DVT patients, in order to provide a better thrombolysis effect and patient comfort. The sphygmomanometer cuff shows a notable increase in the thrombus clearance rate when compared to the use of conventional tourniquet for pressure banding to augment the effect of thrombolytic therapy. The pressure required to compress the superficial veins also showed a notable decrease, leading to better comfort for patients. Patients' lower extremity with acute DVT will result in severe swelling, cyanosis and pain, causing lower extremity dysfunction, even the vein thrombosis syndrome.[29] Previous studies showed that the incidence of PTS will be more than 50% after DVT formation.[30] Xu et al compared the efficacy of AngioJet group and catheter-directed thrombolysis (CDT) group for the DVT, and found that the clear thigh detumescence rate (72.19%±19.55% vs 65.35%±17.26%) and calf detumescence rate (62.79%±18.56% vs 55.75%±17.27%), respectively, which showed AngioJet thrombectomy has stronger clearance ability compared to CDT.[31] The sphygmomanometer group (group A) in our study has higher detumescence rate and thrombus clearance rate than the AngioJet group. Moreover, Li et al evaluated the difference of clearance between AngioJet thrombectomy plus CDT and the manual aspiration thrombectomy (MAT) plus CDT for acute DVT. The results showed that the AngioJet thrombectomy (thrombus

Table 5

Comparison of postoperative VAS score of patients' calf in two groups.

Group	Number of cases	postoperative 6 h	postoperative 24 h	postoperative 48 h	postoperative 72 h
Group A	40	1.68±0.62	1.20±0.56	0.48±0.51	0.20±0.41
Group B	40	3.83±0.71	2.53±0.64	1.60±0.55	0.65±0.53
P		<.001*	<.001*	<.001*	<.001*

Data are expressed as mean±SD.
* $P<.05$.

clearance is 98.36%) is as effective as MAT (thrombus clearance is 98.36%) for acute iliofemoral DVT.[32] The thrombus clearance in this study was higher than the efficacy of group A and group B in our present study.

The main aim of quick clot clearance is to eradicate the thrombus from the occluded venous segment and establish unhindered blood flow so as to minimize the complication of PTS.[27] Deep venous embolus often break off that can cause blood reflux and then develop into lethal PE.[33] The key point of the thrombolytic therapy is to keep adequate drug concentration early and effectively, restore blood flow patency, and maintain normal valve function.[34] Thus, the medication route and method are essential. The possible complications associated with the locoregional thrombolytic therapy is bleeding, including major bleeding like intracranial bleeding.[35]

In recent years, during thrombolytic therapy, the continuous infusion of low dose urokinase via dorsal foot superficial vein combining with the tourniquet ligated at 10 to 15 cm proximal to the ankle joint is very common in clinical use.[8,10,19] The possible reason may be due to the presence of multiple communicating branches among the deep and superficial veins of lower limb. There exist four groups of communicating branches in the boot area of foot which play pivotal roles in clinical therapy.[23] According to this anatomical principle, the tourniquet is used to block the superficial vein of lower extremity so as to increase the drug concentration at the lesion site. Thus the tourniquet has become one of the most prevailing auxiliary nursing tools.[36] Nevertheless, many limitations still exist. First, the tourniquet is operated manually so that many subjective factors should be considered and the pressure of blocking the blood flow cannot be determined. If too tight, the tourniquet will block both superficial and deep veins, or even block the artery, that may lead to serious consequences. If too loose, the tourniquet cannot block the blood flow of superficial vein effectively, or fail to achieve the expected optimal effects of thrombolysis. Secondly, due to the differences of the age, gender, and limb circumference of the patients, the pressure level of the tourniquet cannot be measured accurately because of the lacking of the objective operating standards. Since the ligation procedure is almost based on the experience of a nurse, it is difficult for a nurse to perform a constant pressure level that will lower the efficacy of treatment.

Furthermore, the patients who receive multiple repeated ligations using the tourniquet may have redness, wrinkles, obvious pain, and other complications in their skins. To address this issue, this study used the dial sphygmomanometer to optimize the inflated pressure parameters accurately and guide the setting of the pressure value during thrombolytic therapy, according to the deep venous imaging during the lower extremity venography. In this way, we ensure that more thrombolytic drugs can infuse into the deep vein during the whole treatment process so as to improve the effect of local drug concentration. Moreover, the dial sphygmomanometer cuff has wide contact with the skin of the affected limb, which is not easy to cause pain, skin redness, wrinkles, and other comorbidities so that it is more comfortable for patients.[37]

Nonetheless, although the inflation pressure parameters can be set using this nursing tool according to treatment needs, there still exist several limitations. First, the dial sphygmomanometer cuff is specially designed according to the circumference of the patients' upper limb.[38] As the calf circumference of lower extremity in the DVT patients is larger than healthy controls, the cuff may be too small for ligating. Moreover, because of the wide cuff, the superficial vein blood flow still cannot be blocked in some patients even if the pressure exceeds 80 mmHg during the therapy. To overcome this problem, we have developed a new sphygmomanometer tool and applied for a practical novel patent product (Intelligent Airbag Pressure Cuff, patent number: ZL201620089062.9). In addition, since the present study is just from single center with a limited number of cases, a joint multicenter study and longitudinal investigations are required in the future study.

5. Conclusions

In summary, compared with the tourniquet, using the dial sphygmomanometer cuff to block the superficial vein of lower extremity blood flow will obtain a better thrombolytic effect, higher patients' comforts during the treatment process, and provide a simpler and easier nursing tool that is worth spreading in clinical use.

Author contributions

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Writing – original draft: Yan Li.
Writing – review & editing: Yu-Chen Chen, Jian-Ping Gu.

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